Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University
SESSION: SIG 2: Study Conduct Breakout

Session Information	**Date: May 30, 2007** **Time: 1:30 p.m.–4:30 p.m. PDT** **Presenter/Lead: George Komatsoulis, Wendy Patterson** **Facilitator: Mark Adams** **Scribe: Daniela Smith**
Executive Summary	Session participants reviewed the scope of eight Study Conduct projects, including caMatch (Prescreening), Central Clinical Participant Registry (C3PR), Cancer Central Clinical Database (C3D), Vendor Systems, caXchange, Patient Study Calendar (PSC), Financial/Billing, and Library of Standard Case Report Forms (CRF). Participants received an overview of each project or activity and discussed scope validation and requirements in the context of Intellectual Property Value, Data Sensitivity, Institutional Review Board (IRB) Institutional Restrictions, and Sponsor Restrictions.
Discussion	**Study Conduct SIG Projects/Activities Discussion** caMatch (Prescreening)—Mary Jo Deering • Participants discussed automated screening tools versus manually used tooling for the Physician's Data Query (PDQ) and clinicaltrials.gov. • Will different institutions maintain their own data or submit it to a master registry? There are also questions concerning incorporating patient eligibility criteria into a trial (i.e., who would govern, who would have access). • The institution should have control over the public interface and public access to data. • There are questions concerning what type of information is should be retained and where (e.g., local retention by patient choice or through cookies/repositories in personal machines). • Technology needs to inform the patient of new matches *with their consent.* • caMatch will work with or without patient-identifiable data. • Is there any way to extract patient-identifiable information from caMatch when it has been entered? • Can someone other than the patient extract PHI (Protected Health Information)? C3PR—Patrick McConnell • Would all participating sites in multi-site trials use the same central repository? There are different options for different coordinating sites. • In the context of a multi-site trial, is there one repository of participant information? The answer depends on whether affiliate or local sites concur on how the study is being run; deployment could be on a variety of scales. • There are concerns concerning the accessibility of all available data classes and the importing and exporting functionality of patient information. C3D—Dianne Reeves • Only Duke University has local on-site installation of C3D. • How are data that are not exposed explicitly through the interface retrieved? There is a tool called I-Review that queries the system and reports back.

- Anything potentially captured by a CRF could be loaded in C3D.
- The Clinical Trials Object Model (CTOM) application programming interface (API) is grid-enabled for C3D and potentially for any system that could support that data model. CTOM is considered a way for multiple systems sharing data quickly.
- Would CTOM work with any Clinical Trial Management System (CTMS)? Yes, as long as there is a way to map data from the CTMS to the CTOM object model.
- The CTOM repository could be filled with legacy data as long as the data are bound appropriately by the data elements that describe them.
- PHI is identified data subject to Health Insurance Portability and Accountability Act (HIPAA) and regulatory review.
- Sponsorship restrictions include—
  - With NCI as sponsor, there are low barriers to sharing.
  - Private sponsors will want restrictions.
  - Restrictions will be defined sponsor-by-sponsor (and study-by-study).

Vendor Systems—George Komatsoulis

- Vendor systems will be not affect data sharing decisions significantly.
- What are the differences between C3D and other vendor systems? There are no differences from the data sharing point of view, other than C3D is currently the only vendor system that is based on Common Data Elements.

caXchange—Smita Hastak

- What types of laboratory data (e.g., localized patient registry, local pharmacy) would institutions be willing to share?
- The business problem is how to help hospitals and cancer centers integrate systems internally. The goal is to convert laboratory data to a standardized format and put into a CTMS.
- Translational research could be enabled through caXchange. This is an opportunity to work toward extending opportunities to other systems (including extensions to other domain Workspaces).

PSC—Warren Kibbe

- Interested participants may help in evaluating the upcoming PSC Release 2 (June 1, 2007).
- What sort of data do you retain and reuse? Information about the patient (i.e. patient identifiers) that is organized by protocol is shared and retained.
- Event–driven data does not include the laboratory data itself. The PSC is a portal for arranging that data.

Financial/Billing—Sorena Nadaf

- Who is billing whom? What is the insurer, sponsor, or individual allowed to pay for?

Library of Standard CRFs—George Komatsoulis

- A question was raised concerning inclusion of proprietary information in CRFs. These CRFs should be available in a public repository. When the sponsor is industry or another non-government entity, there could be intellectual property constraints. If another organization is not willing to share questions, this information will not be captured in the harmonization activity, posing a risk to data sharing and interoperability.
- There was discussion concerning standardizing content (CRF questions) versus structure. There is a related activity under the Reporting/Sharing SIG known as the Electronic Data Capture Instrument (eDCI), an HL7 data capture instrument. The implementation of standardized forms should be standardized across a generic platform.

- Does this activity roll up to the Inter-Agency Oncology Task Force (IOTF)? IOTF focuses on Food and Drug Administration (FDA) data, which is more in the scope of reporting to regulatory agencies. A significant driver to the content FDA wants is regulatory and sponsor reviews.
- There are similarities in CRFs between the CRF Library and Clinical Data Acquisition Standards Harmonization (CDASH), but they are not necessarily congruent. (CRF is more specific to oncology.)
- There are questions concerning the funding source for CRF; there seems to be no single clean source. There is a need to accommodate non-NCI originating sources.
- CRFs are the forms themselves, not the data within them.
- There are no IRB issues once the form is standardized. IRB restrictions might prevent later use, but the creation of the form itself is not restricted.
- Do non-NCI sponsors have concerns?

Parking Lot/Issues

- Specifics depend on the system and its capabilities.
- Hacking the system is not a data sharing issue.

Requirements

Req. #	Name	Description
Study Conduct-R1	Data Determination	What is shared is determined by application design. The solution may be an application or warehouse that can share de-identified data.
Study Conduct-R2	Architectural Requirements	In order for caBIG™ to proceed, the basic architectural guidelines for data sharing must be considered (i.e., what applications will always require agreement(s) and what mechanisms will be needed for sharing that data).
Study Conduct-R3	Data Sharing Requirements for Grid	Data sharing requirements for sharing over Grid must be determined.
Study Conduct-R4	De-identified Data Mechanism Identification	There is a need to identify other mechanisms for sharing data (in a de-identified data set, etc.) to allow data sharing to go forward.

Issues

Issue ID	Description
Study Conduct-I1	How much PHI is needed to produce useful clinical trial results?
Study Conduct-I2	Can we define a linked data set that we can easily start to share out?
Study Conduct-I3	There are questions concerning the type of information is being retained and where (e.g., local retention by patient choice or through cookies/repositories in personal machines).
Study Conduct-I4	Should the shareability of individual data elements in our standard data models (such as CTOM) be identified to facilitate sharing of those portions of the data that can be shared?

Action Items

No action items were identified.

Attendance

#	First Name	Last Name	Affiliation
1.	Mark	Adams	Booz Allen Hamilton
2.	Bob	Annechiarico	Duke University
3.	Laura	Bradley	OHSU
4.	Don	Connelly	Univ. of Minnesota
5.	Mary Jo	Deering	NCI CBIIT
6.	Amy	Funkhouser	ECOG
7.	Meg	Gronvall	Booz Allen Hamilton
8.	Sonja	Hamilton	Mayo Clinic
9.	Robin	Harris	Univ. of AZ Cancer Center
10.	Smita	Hastak	ScenPro
11.	Virginia	Hetrick	Patient Advocate
12.	Andrea	Hwang	UC Irvine
13.	Kim	Johnson	CALGB
14.	Warren	Kibbe	Northwestern University
15.	George	Komatsoulis	NCI CBIIT
16.	Bob	Lanese	Case Western
17.	Jieping	Li	Georgetown University
18.	Jack	London	Kimmel Cancer Center (TJU)
19.	Patrick	McConnell	Duke University
20.	Sorena	Nadaf	Vanderbilt University
21.	Niket	Parikh	Booz Allen Hamilton
22.	Wendy	Patterson	NCI TTC
23.	Kerri	Phillips	PercipEnz
24.	Gopi	Potnuru	PercipEnz
25.	Dianne	Reeves	NCI CBIIT
26.	Peter	Schad	NCI DCCPS
27.	Linda	Schmandt	Univ. of Pittsburgh
28.	Angela	Smith	SWOG
29.	Daniela	Smith	Booz Allen Hamilton
30.	Terri	Stewart	UNM CRTC
31.	Rhett	Sutphin	Northwestern University
32.	Umit	Topaloglu	UAMS
33.	Troy	Walls	Univ. of Arkansas for Medical Sciences
34.	Sean	Whitaker	Northwestern University
35.	Julie	Zhu	Northwestern University